(m) Tartrate-containing active ingredients. Tartaric acid or its salts; maximum daily dosage limit 200 mEq. (15 grams) of tartrate.

[39 FR 19874, June 4, 1974, as amended at 51 FR 27763, Aug. 1, 1986; 55 FR 19859, May 11, 1990]

§ 331.15 Combination with nonantacid active ingredients.

(a) An antacid may contain any generally recognized as safe and effective nonantacid laxative ingredient to correct for constipation caused by the antacid. No labeling claim of the laxative effect may be used for such a product.

(b) An antacid may contain any generally recognized as safe and effective analgesic ingredient(s), if it is indicated for use solely for the concurrent symptoms involved, e.g., headache and acid indigestion, and is marketed in a form intended for ingestion as a solution.

(c) An antacid may contain any generally recognized as safe and effective antiflatulent ingredient if it is indicated for use solely for the concurrent symptoms of gas associated with heartburn, sour stomach or acid indigestion.

Subpart C—Testing Procedures

§ 331.20 Apparatus and reagents.

(a) pH meter, equipped with glass and saturated calomel electrodes.

(b) Magnetic stirrer.

(c) Magnetic stirring bars (about 40 mm. long and 10 mm. in diameter).

(d) 50 ml. buret.

(e) Buret stand.

(f) 100 ml. beakers.

(g) 250 ml. beakers.

(h) 10 ml., 20 ml. and 30 ml. pipets calibrated to deliver.

(i) Tablet comminuting device.

(j) A number 20 and 100 U.S. standard mesh sieve.

(k) Tablet disintegration apparatus.

(l) 0.1 N, 0.5 N and 1.0 N hydrochloric acid.

(m) 0.5 N sodium hydroxide.

(n) Standard pH 4.0 buffer solution (0.05 M potassium hydrogen phthalate).

(o) 95 percent ethanol.

(p) Purified Water U.S.P.

[39 FR 19874, June 4, 1974, as amended at 40 FR 48343, Oct. 15, 1975]

EFFECTIVE DATE NOTE: At 61 FR 4823, Feb. 8, 1996, § 331.20 was removed, effective February 10, 1997.

§ 331.21 Determination of percent contribution of active ingredients.

To determine the percent contribution of an antacid active ingredient, place an accurately weighed amount of the antacid active ingredient equal to the amount present in a unit dose of the product into a 250 ml. beaker. If wetting is desired, add not more than 5 ml. of 95 percent ethanol and mix thoroughly to wet the sample (ethanol may affect the acid neutralizing capacity). Add water to a volume of 70 ml. and mix on magnetic stirrer at 300±30 r.p.m. for about one minute. Analyze the sample according to the procedure set forth in § 331.26 and calculate the percent contribution of the antacid active ingredient in the total product as follows:

Percent contribution=(Total mEq. Antacid Active Ingredient×100)/(Total mEq. Antacid Product)

EFFECTIVE DATE NOTE: At 61 FR 4823, Feb. 8, 1996, § 331.21 was redesignated as § 331.20, and revised, effective February 10, 1997. For the convenience of the reader, the revised text is set forth below.

§ 331.20 Determination of percent contribution of active ingredients.

To determine the percent contribution of an antacid active ingredient, place an accurately weighed amount of the antacid active ingredient equal to the amount present in a unit dose of the product into a 250-milliliter (mL) beaker. If wetting is desired, add not more than 5 mL of alcohol (neutralized to an apparent pH of 3.5), and mix to wet the sample thoroughly. Add 70 mL of water, and mix on a magnetic stirrer at 300±30 r.p.m. for 1 minute. Analyze the acid neutralizing capacity of the sample according to the procedure provided in the United States Pharmacopeia 23/National Formulary 18 and calculate the percent contribution of the antacid active ingredient in the total product as follows:

Percent contribution = (Total mEq. Antacid Active Ingredient x100)/(Total mEq. Antacid Product).

[61 FR 4823, Feb. 8, 1996]

§ 331.22 Reagent standardization.

Standardize the sodium hydroxide (NaOH) and hydrochloric acid (HCl) solutions according to the procedures in the United States Pharmacopeia XVIII